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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,625	06/27/2003	Shelby L. Cook	022956-0214	9377
21125 7590 04/23/2008 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER NGUYEN, TUAN VAN	
			ART UNIT 3731	PAPER NUMBER
			NOTIFICATION DATE 04/23/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No. 10/615,625	Applicant(s) COOK ET AL.	
	Examiner TUAN V. NGUYEN	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 March 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In previous Office action, claims 1-19 and 21-25 were pending. Claims 1-19 and 21-25 were examined and rejected.

Response to Amendment

2. According to the Amendment filed on January 22, 2008, claims 6-7 and 21-25 have been canceled. Accordingly, claims 1-5 and 8-19 are pending in this present application.
3. Examiner acknowledges corrected drawing sheets in compliance with 37 CFR 1.121(d) have been filed. No new matter is added.
4. Examiner acknowledges Declaration under 37 C.F.R. 1.132 was filed on January 22, 2008. The Declaration has been fully considered but they are not persuasive because no objective evidence of commercial success is included in the Declaration.
5. Applicant's arguments with respect to the rejections under 35 U.S.C. 102 and 103 have been fully considered but they are moot in view of new ground of rejection.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. **Claim 19 is rejected under 35 U.S.C. 102(e) as being anticipated by Donnelly et al. (U.S. 6,773,436).**
8. Donnelly et al discloses (Figs. 9A-9D and col. 8, lines 16-65) a method of attaching tissue to a bone in a patient's body comprising the step of: providing suture anchor; forming a bone cavity (Fig. 9B); securing the suture strand to a portion of tissue to be attached to bone (Fig. 9C); inserting the suture anchor into the bone cavity and toggling the suture anchor by pulling the suture (Fig. 9D).
9. With respect to the recited structure limitations of the anchor, it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
12. **Claims 1-5 and 8-18 are rejected under 35 U.S.C. 103(a) as unpatentable over Pedlick et al. (U.S. 6,270,518) in view of Barlett (US 5,626,612).**
13. Pedlick discloses (see Figs. 35-36 and 38-41) a bioabsorbable suture anchor 301 for anchoring tissue to a bone, comprising: an elongate body 310 defined by a longitudinal axis; a first, leading end 302, includes a rounded distal end 304, and a second, trailing end 306; the elongate body comprising two opposed surfaces 320 between the first and second ends, and a plurality of sidewalls 312, 316 extending between the two opposed surfaces; a flared portion 308, includes biting edge 322 formed on the second end and extending from one of the sidewalls, the flared portion being adapted to engage and anchor into bone tissue; and a suture channel 330, that includes rounded edge 330 on both sides, formed in the elongate body for passage of a suture strand therethrough, the suture channel extending between the two opposed surfaces, and strand of suture is inserted through the channel, and the center of the channel is offset from the longitudinal axis of the anchor (see Fig. 41); wherein the suture anchor is configured to toggle and anchor inside a bone cavity by the suture; and the anchor also includes a

blind hole 334 for engaging with insertion tool (see Fig. 36), wherein the insertion tool having elongate member with a proximal, handle end and a distal, attachment end (see col. 14, lines 1–60). Pedlick also discloses the method of deployment the anchor into a bone hole as claimed in claim 19-20 (see col. 18, line 53 to col. 19, line 55).

14. The device of Pedlick discloses the invention substantially as claimed except for suture channel is laterally offset from the longitudinal axis of the anchor in a direction opposite the direction of the flared portion. Noting that Pedlick discloses the suture opening or channel 5 of embodiment as shown in Fig. 1 is offset from the center of the anchor for the purpose of toggling the anchor (col. 8, line 68 to col. 9, line 4) and Bartlett discloses (Fig. 7 and col. 8, lines 53-65) suture anchor comprising, among other things, a suture channel 36 that is laterally offset from the longitudinal axis of the anchor. Apparently, the advantage of the suture bore located laterally offset from the centerline of the anchor is for preventing detrimentally effecting the strength of the suture anchor. It has been held that substitution one known element for another to obtain predictable results is old and well known in the art, therefore, it would have been obvious to substitute the hole of Pedlick anchoring device as shown in Fig. 35 with the hole as disclosed by Bartlett wherein the hole is offset from the center of the anchor for the purpose of toggling the anchor and preventing detrimentally effecting the strength of the suture anchor. Further, applicant has not disclosed that the suture channel that is laterally offset from the longitudinal axis of the body provides an advantage, or

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solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the suture channel of Bartlett device, Pedlick device, and applicant's invention, to perform equally well.

15. Referring to **claims 2, 3, 14, 15, 17, and 18**, noting that Pedlick discloses the diameter size of suture anchor is 3 mm and the suture anchor having an overall size smaller than conventional bone anchors (see col. 9, lines 20-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to design a suture anchor having elongate body is in the range of about 2-6 mm and the width of the anchor is about 1 mm to about 3 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Extrinsic evidence, Cassidy (U.S. 6,280,474) discloses a bone anchor can be used to attached small bone to small bone or soft tissue to bone (see Figures 11B and 6B and col. 3, lines 29-38) wherein the overall dimensions of the anchor is 1 mm to about 6 mm wide and between 3 mm to 30 mm long (see col. 3, lines 62-65).
16. Referring to **claim 14**, Pedlick discloses the suture anchor may be made of bioabsorbable or non-bioabsorbable polymer such as stainless steel (see col. 10, lines 45-61). It is old and well known in the art that polymer and stainless steel has its own natural color. The natural color of the material that made the suture anchor can be used as visual indication by the naked eyes of the surgeons during the surgery or by X-ray after the surgery (Stainless steel exhibits radiopaque property)

for the indication of the location of the anchor in the surgical site. It is old and well known that color such as yellow, red, and blue enhancing the ability of visual recognition to the human eye. Therefore, it would have been obvious to one of ordinary skill in the art to use blue dye to cover the nature color of the stainless steel and polymer because the blue color would enhancing the visual recognition to the surgeon as compare to the nature color of stainless steel and polymer. Further, Applicant has not disclosed that the blue dye provides an advantage, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the color of Donnelly et al device, and applicant's invention, to perform equally well.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731